Revised Meeting Summary
Organ Transplant Work Group
Second Meeting, January 7, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Work Group Member Attendees:

Charles Alexander
Lori Brigham
Clive Callender, M.D.
Deborah Campbell
Claudia Donovan, M.D.
David Klassen, M.D.
Linda Ohler
Susan Ostovitz
Jessica Quintilian
Bill Rayfield, M.D.
Nicole Stallings
Brigitte Sullivan
Anne Weiland

Commission Staff Attendees:

Eileen Fleck, Chief, Acute Care Policy and Planning
Rebecca Goldman, Program Manager
Paul Parker, Director

Other Attendees:

Pat Cameron
Natasha Gill
Spencer Wildonger

Introductions

Ms. Eileen Fleck opened the meeting by introducing herself and asking the members present and participating by phone to introduce themselves. Ms. Fleck noted that Dr. Clive Callender and Linda Ohler were expected to attend the meeting as well.

Review of Meeting Minutes

Ms. Fleck stated that several members submitted comments or changes to the previous meeting's minutes. Ms. Jessica Quintilian noted a few typographical errors and clarifications. Ms. Anne Weiland requested the following clarifications: On page 5 in the first paragraph, the last couple of sentences were changed to better reflect the intent of the person speaking; on page 9 at the end of the second full paragraph, changes were made to clarify comments by Dr. Claudia Donovan. Dr. Donovan also submitted clarification on her comments on page 9 towards the end of the first full paragraph. Staff made changes in response to these comments.

Before today's meeting, Susan Ostovitz noted an additional change that should be made on Page 5 in the second paragraph that reads, *"For a stand-alone pediatric program, the national minimum volume requirement is higher than that for hospitals with both adult and*

pediatric programs. This is related to the fact that surgeons performing adult transplants have expertise that is transferable to pediatric transplants as well." The existing minutes do not reflect what she said. She is not certain that there is a minimum volume requirement for a pediatric program and suggested that the statements be deleted. Ms. Fleck asked if everyone was in agreement with that deletion; all members agreed.

Ms. Fleck offered to allow a few additional days for the members to review the minutes again. Ms. Brigham stated that she would like to review the document one more time. Ms. Fleck agreed to give the group additional time.

Review of White Paper

Ms. Fleck reviewed corrections made to the White Paper. These were included in an email to the group. In Table 3 on page 13, several numbers were revised. Originally, the total transplant figures included organs that were recovered, whether the donor was living or deceased. Based on concerns raised by one work group member, Staff decided to include only organs recovered for transplantation from deceased donors. No one objected to this change. The corrected White Paper also has a more detailed description of the sources of data for Table 3. As a result of correcting Table 3, the discussion of Table 3 changed too. Initially, there appeared to be a significant difference in the number and rate of kidney transplants for the two organ procurement organizations (OPOs). Upon revision, the difference in the rate of kidney transplants between the two OPOs is half of what was originally presented in the paper (down from 67% higher per million population in the Maryland region compared to the D.C. region to 36% higher in the Maryland region than the D.C. region).

Ms. Weiland questioned whether the intestine transplantation volumes reported on page 11 were accurate because her programs performed more transplants than shown in Table 2. Ms. Sullivan noted that the volumes listed on page 11 reflect transplantations for the residents originating in that OPO's DSA region, which could have been performed elsewhere. Ms. Goldman confirmed that Ms. Sullivan was correct. Table 2 reflects the number of residents from a given region who received an organ transplant anywhere; the use rates are calculated based on the estimated total population for each region. Ms. Goldman later further explained that the data includes residents originating from all the counties and jurisdictions covered within the two DSAs, whether in Maryland or not. Additionally, residents who originate in other DSAs and migrate into the Maryland and Washington Region DSAs for transplants are not included in these figures.

Lori Brigham commented that the nomenclature used in the White Paper adds to confusion. Rather than using *"WRTC OPO"* and *"LLF OPO"*, she suggested that Staff consider using the term *"Donation Service Area"* because the OPOs are not performing transplants. It seemed to be implied that the OPOs are responsible for the number of transplants. The Donation Service Area (DSA) encompasses the transplant centers and the OPOs. Mrs. Goldman agreed to make changes in response to her comments, noting that the assessments presented in the White Paper were not intended to be presented as a function of the OPOs. Other workgroup members agreed that changes should be made to address the concern raised by Ms. Brigham.

Dr. Donovan asked if the numbers in Table 2 on page 11 included organs collected but not transplanted. Ms. Goldman responded that Table 2 includes the actual number of transplants for residents from a given service area. Ms. Fleck concurred. Ms. Weiland suggested that the White Paper state that more explicitly.

Ms. Brigham asked if Table 2 included only transplants performed by transplant centers in the WRTC or LLF region. She did not think that the data was available by zip code. Ms. Fleck explained that staff received data by the region of residence and used the information for the need projection. Staff considers if a patient lives in the Donation Service Area of the LLF, but received the transplant in the WRTC region or somewhere other than those regions. The idea is to understand, for the population residing in the service areas which include Maryland residents, how many organ transplants are taking place on residents and for which organs, no matter where the transplant takes place.

Follow-Up on Pediatric Kidney Transplant Program Information

Ms. Fleck wanted to follow up on a question from the last meeting regarding the number of kidney transplants performed in pediatric hospitals and mixed programs. Staff distributed a handout via email prior to the meeting and again at the meeting. The information on this handout shows that no pediatric hospital in the United States performed more than 30 transplants in CY 2013. The greatest volume was 28, with most hospitals performing under 20. The average number of transplants for recipients under 18 years of age at any center was approximately 11. This number is much lower than the threshold of 30 for kidney transplant centers in the existing State Health Plan (SHP).

Ms. Fleck asked if anyone had a recommendation regarding changes to the SHP based on this information. Ms. Sullivan, who raised the issue at the last meeting, commented that she does not want there to be a separate set of volume criteria for pediatrics, but she would like acknowledgement that pediatric programs operate at a lower volume than adult programs. Specifically, for the SHP threshold volumes, she thinks that Children's Hospital should not be expected to operate on the same level as all other programs. Ms. Fleck added that she thought Ms. Sullivan's concern was based on the assumption that the Commission would not consider adding a new adult kidney program in a dedicated region as long as the pediatric kidney program is well below the 30 threshold. Ms. Weiland agreed that the need for an adult program should not be determined by the volume at the pediatric program. She noted that UNOS got rid of a pediatric volume requirement. Dr. Klassen added that most pediatric transplants take place in adult programs. Ms. Sullivan suggested that a differentiation be added to the revision of the SHP.

Ms. Fleck announced the arrival of Linda Ohler and Dr. Clive Callender. Dr. Callender expressed concern that focusing on volume thresholds made quality irrelevant and wanted to point out that these volumes do not speak to the quality of these programs. Several workgroup members agreed that quality was also important.

Policies Regarding Access to Services

Ms. Goldman began a discussion on existing policies in the SHP chapter for organ transplants and one standard that may be relevant to a discussion about changes to the need projection methodology. She noted that Policy 12 states that organ transplantation services should be located within a three-hour one-way drive time to at least 95 percent of Maryland's population. In other chapters of the SHP, the drive-time standard for defining reasonable access is different. For example, there is a 30 minute drive time for 90 percent of the population listed for acute care services, a two to three-hour drive time for neonatal services, and a two-hour drive time for cardiac surgery services. The three-hour drive time standard in this SHP chapter allows for the location of organ transplant services in Baltimore. Ms. Goldman asked for feedback from the workgroup members on whether they think this is still an appropriate drive time for accessibility.

Ms. Weiland asked if this drive time was specified based on the size of Maryland. Ms. Goldman confirmed that was the rationale and that these services were centrally located in the medical hub of the state. Members were asked if they were in favor of maintaining the policy without changes. A few members stated that the drive time standard was long. Dr. Donovan stated that for such a specialized service she did not believe the drive time was excessive. Ms. Goldman commented that in surrounding states, it seems they might have even longer drive times. Dr. Campbell added that in Virginia, travel could be four hours within one planning region. Dr. Klassen felt that a three-hour drive time was an appropriate policy. The discussion concluded with Ms. Goldman asking if everyone was in agreement with maintaining the current policy. No member expressed disagreement.

Ms. Goldman introduced the next issue, defining disparity in organ transplantation. She reported that this was a common topic in organ transplantation literature, and she wanted to understand how to use any data available to ultimately better serve organ transplantation patients and donors in Maryland and the region. She noted that UNOS recently amended its allocation policies to improve access for minorities and maximize use of potential donor kidneys. This change has the potential to reduce disparities, but the data needed to evaluate the impact of the new allocation policies is not yet available.

Ms. Goldman noted that one of the disparities presented in the White Paper was the difference in the use of living donors, measured by both volume and rates, in the Maryland DSA as compared to the Washington, D.C. DSA. The Maryland DSA's living donor numbers are greater than the D.C. region's numbers. Additionally, Ms. Goldman noted that the wait list is longer for the Maryland DSA than for the Washington, D.C. DSA. She asked if there was anything that could be incorporated into the SHP to promote living donation, or to better understand and respond to the wait list data, or how to handle differences in transplant rates for the two DSAs.

Dr. Klassen commented that people on the wait list may be from out of state, including from Pennsylvania, New Jersey, and New York. They could also be on both the wait lists in the Maryland and D.C. region. This should be considered when evaluating access and need. Ms.

Goldman stated that these comments will help staff understand the need to account for anyone out of state or double-counted on the wait lists, for example. Mr. Alexander added that donor numbers have been fairly stable across the country. There has been small growth from year-to-year, and there is potential to increase the number of living donors.

Ms. Fleck asked if the members thought MHCC should incorporate anything into the SHP chapter for organ transplants in order to try to reduce disparities in transplant rates. Mr. Alexander commented that from an organ availability perspective, this group could make a strong case that any growth in living donation would benefit the system. Ms. Weiland questioned how these issues could be regulated through the SHP. Ms. Fleck responded that while this group does not have the ability to change national policy or decide who gets what organs or influence clinical decisions, the SHP chapter could address other opportunities and include policy statements or standards that might be beneficial.

Ms. Weiland asked Ms. Fleck for specific ideas. Ms. Fleck responded that in terms of setting expectations for those proposing a new program or adding a program, the SHP chapter for organ transplantation could include a standard that requires applicants to demonstrate what they will do to promote or increase organ donation. For example, should they have an educational program? The SHP chapter could include requirements, if the group feels it should, or it could not include these types of criteria if the group feels they are not appropriate.

Ms. Brigham stated that any transplant center's commitment to transplantation has to go hand-in-hand with promoting organ donations. She agreed that new programs should demonstrate their metrics in terms of organ donation and their commitment to that process. If an organization does not have a commitment to donations, it should not do transplants. Ms. Goldman asked for an example of measurable criteria for commitment to donations. Ms. Brigham responded that there are national metrics available. Data is collected to help answer such questions. She provided several examples: Are the centers referring enough potential donors? Are they done in a timely manner? Are there appropriate requests for donations that are outlined? Do they have a donation committee? What type of programs do they have internally that support donation as an institution? Ms. Brigham noted that the answers to these types of questions are tracked by the Joint Commission.

Ms. Weiland commented that the OPO is responsible for several of those metrics mentioned, not the transplant programs. The transplant centers do their very best to positively influence all the metrics because organ donation is integral to the survival of a transplant program. Dr. Callender noted that this was true in theory, but sometimes not reality. Ms. Brigham clarified that while the transplant division has a commitment to transplantation, translating that to critical care, trauma, and emergency departments can sometimes be difficult. She believes that if MHCC is considering a proposed new program, the institution proposing it should have to demonstrate a strong commitment in some capacity to organ and tissue donation. Dr. Callender agreed. Ms. Sullivan added that she would like to see a commitment to living donation.

Dr. Klassen commented that the two transplant hospitals in Maryland are already highly incentivized to promote donations in all facets; consequently, the SHP chapter cannot effectively suggest a metric to which transplant hospitals should aspire. Hospitals already do what they can. However, he added that there are many other hospitals, and donors come from all over; if there's a way to increase donor referrals from the other hospitals, it may be beneficial. Ms. Brigham stated that if a new hospital seeks to implement a new transplant program, then the MHCC should be sure that the hospital has the same level of commitment as the existing institutions in Maryland.

Dr. Donovan asked how that commitment would be measured. Mr. Alexander agreed that defining program effectiveness would be a difficult task. He added that outcome measures are tracked in other places in terms of actual donors, potential donors, and referral rates. He was unsure about how to determine the appropriate levels. Dr. Callender responded that it may be difficult, but it should be done. He added that the number one problem in organ transplantation is the shortage of donors. Mr. Alexander continued that his point was that "commitment" to a donor program would be difficult to measure, but that is not to say that it cannot be measured.

Ms. Sullivan referred the group to page 31 in the current SHP chapter. There is a requirement that an applicant describe relevant preventive services for health promotion and disease prevention. She thought that they were talking about something similar – not necessarily a numeric metric, but a demonstration of having plans in place for outreach for living donations or that a hospital is engaged in an appropriate level of deceased donations. Ms. Brigham stated that along with the data collected by the Joint Commission referenced above, there are CMS requirements that organ transplantation programs must report every death to the OPO.

Ms. Goldman stated that the discussion at hand should revolve around hospitals' proposals to establish new transplant programs. Dr. Donovan asked for additional clarification on whether this group should be talking about requirements for existing programs or for new applicants. Ms. Fleck stated that for new programs, the Commission is asking what to look for from an applicant seeking to establish a new program. For example, should MHCC expect an applicant to demonstrate that the program can be successful, especially in the area of disparities? If a hospital feels that its proposed program can better serve particular service areas, is that something that should be evaluated by MHCC? Ms. Weiland indicated that it is hard to speculate and impossible to know the outcome until the program is up and operating. Ms. Weiland expressed support for the existing language and uncertainty over whether adding more detailed requirements makes sense.

Ms. Fleck noted that the MHCC needs to determine when there is a need for a service. For example, should disparities indicate a need for a new program? Dr. Klassen stated that the group should define any specific disparities, if they are going to be addressed. Dr. Callender added that the donor disparity is a disparity he would like to see addressed. Ms. Goldman then asked the work group members how they believe the SHP chapter for organ transplants should address specific disparities.

Ms. Fleck gave the example of relatively fewer kidney transplantations taking place in one DSA, even though the prevalence of kidney disease in that same area is higher than another area where there are more kidney transplantations. Is that a case where MHCC could take an action to benefit the apparently underserved area? Ms. Weiland repeated that there are many different pieces in the specialized field of organ donation. There are different people and environments in each transplant center; OPO performances differ; community hospitals have different interests in performance; there are biases in different populations. She thought it would be difficult for MHCC to determine which aspects are affecting which outcomes, and MHCC cannot regulate one piece of a larger, complicated puzzle. Dr. Callender countered that language should be included that requires a new center be involved in getting communication out to the public regarding organ donation. He added that certain metrics can be defined down the road, but new centers should be able to demonstrate commitment, promotion, prevention, and identify ways they are going to improve organ donation through community outreach programs.

Dr. Klassen did not see the harm in having a statement that requires applicants to demonstrate historical commitment to organ donation. Ms. Weiland agreed. Dr. Klassen also stated that measuring disparity is difficult and hard to define, and he does not feel that making policies around addressing disparities is very useful. Staying with standard measures like those that MHCC already has will be most effective. Dr. Callender stated that he has defined organ donation disparity, and he does not believe that this should be left out.

Ms. Goldman asked that workgroup members email the sources for some of the data discussed at the meeting so staff can review them and investigate ways to compare hospitals and determine the better performers. Ms. Brigham and Mr. Alexander indicated they would help with this.

Policies Regarding Program Quality

Ms. Goldman explained that Policy 6 states a preference for fewer programs with higher volumes instead of more programs at threshold or minimum volumes. She noted that the group expressed that they were in favor of this type of policy during the first meeting. She wanted to provide another opportunity for any additional feedback. No workgroup members proposed changes to Policy 6.

Ms. Goldman explained that Policy 14 states a preference for expansion of an existing program over a new program. Dr. Klassen asked what was meant by the term “expansion of programs.” Ms. Fleck responded that the idea is to assume that existing programs can absorb the additional need for the service, rather than assuming that an additional need for the service indicates that a new program is needed. She added that she is interested in determining the amount of growth that would be required before allowing a new program to be established. Ms. Sullivan commented that it is hard to determine because you are not asking existing programs if they can absorb that projected need. Ms. Fleck replied that this would come up when a new program applies to establish an organ transplantation center, but an existing program reports they can absorb the projected need. For now, Policy 14 seems to indicate that MHCC would prefer that existing programs absorb new growth instead of entertaining a proposal for a new program.

Ms. Weiland stated that she believes the SHP chapter's objective is to ensure access to Maryland residents and to ensure that they have optimal outcomes. She noted that it is well-established that programs with higher volumes produce better outcomes. Dr. Klassen disagreed and said that is not the case in organ transplantation; there are modest programs with great outcomes. He believes volume and quality do not always go hand in hand. However, he acknowledged that there are other reasons to prevent a new program from opening, including cost and duplication of services. There are also thresholds, and expansion cannot be unlimited, but it is hard to set one threshold.

Linda Ohler noted that since 2007, which was after the last time this SHP chapter was updated, transplant programs are more accountable for the quality of the program through the Scientific Registry of Transplant Recipients (SRTR). She noted that having a certain volume does not guarantee a certain level of quality, and the Certificate of Need (CON) process should consider the quality of the program. Ms. Sullivan commented that she would like to look at not only the survival rates but also the transplant rates. Mr. Alexander reiterated that the one thing that is unique about organ transplantation is the finite pool of resources. Instead of having the ability to create more inventory to address need, there is redistribution of a limited resource. He commented that the SHP chapter should also consider transplant rates, acceptance rates, and whether different behaviors in different programs cause a redistribution of resources.

Ms. Fleck summarized that she heard workgroup members calling for this policy to be changed from emphasizing volume to incorporating quality when determining whether existing programs can or should absorb demand. Ms. Weiland suggested adding a quality statement to the existing policy, such as, *"organ donation rates at existing programs should be considered."* Ms. Fleck invited workgroup members to send additional suggestions.

Minimum Volume Standards

According to the existing SHP chapter, a program should cease operations if it falls under the minimum volume threshold. Ms. Ohler pointed out that the minimum volume for a pancreas program is 12, which is a high volume. She added that the volume of pancreas transplants has gone down over time. In the last three years, 14 was the highest number of transplants performed in the two DSAs covering Maryland. Ms. Fleck asked if there was a new minimum volume of transplants that any member wanted to propose. Ms. Sullivan asked if it was necessary to assign a numeric standard for pancreas transplants. She added that it would be pretty unusual for a hospital to propose to start a new pancreas transplantation program without another organ transplant program. In addition, she noted that CMS does not have a minimum requirement. Ms. Goldman confirmed that the recommendation was to revise the pancreas thresholds in line with the current language used for intestine/small bowel, islet cells, hepatocytes, and other transplant programs that reads, *"To be determined by the Commission on a case by case basis, based on the best information available at the time of application."* Workgroup members were in agreement. Ms. Weiland commented, for the record, that several of the managed care plans have thresholds for participation in their Centers of Excellence programs, which she believes are set at about 12 for pancreas.

Dr. Klassen requested clarification on whether a new program was expected to reach minimum volume levels in the first year. Ms. Goldman responded that Policy 4 includes a provision that allows new programs 36 months to meet volume standards after beginning operations. The group was in agreement with this timeframe.

Organ Transplant Utilization/Need Methodology

Ms. Goldman noted that the most recent need projection was included in the White Paper as an Appendix. She briefly went over the methodology by explaining that it is based on historic transplantations performed in the last three years at transplant centers in both of the DSAs that include Maryland jurisdictions. The Certificate of Need application process is considered opened when the projection for new net need exceeds the threshold volume for a program and all existing programs have performed at the threshold volume. The threshold volume is set at 50 for kidney transplantation and 20 for most other organ transplantations. There is currently a net need projection for liver transplants in both regions. Ms. Ostovitz requested that the projections be updated because the number of liver transplants has increased in the past few years. Ms. Sullivan agreed. She added that there has been a recent increase in the number of liver transplants, but they may have leveled off at a higher, though steadier rate in last two years. This exemplifies what she believes is a flaw in the need projection methodology: When an initial spike occurs in the first year of a trend of higher sustained levels of transplantation, the current methodology will project more of a need than may actually exist because the projection assumes the same, continued rate of growth.

Ms. Goldman asked what the best way to improve this methodology might be. She reported that she had researched how other states that regulate organ transplantation through a CON program evaluate the need for new programs. Some other states limit the number of centers available in a planning region. Virginia sets a limit of one center per planning region. Michigan limits a different number of programs depending on organ. Other states project the need for organ transplantation services based on the number of patients eligible for an organ transplant, like those on dialysis or UNOS wait lists. Ms. Goldman asked if members had any specific suggestions about how to improve our current need methodology based on these examples or other examples.

Ms. Sullivan commented that looking at the patients who have organ failure and organ disease is one way to approach it. She suggested considering patients on dialysis or hospitalizations for different kinds of diseases. Ms. Goldman asked about how to address projecting a need for a service that would be greater than the health care industry's ability to provide that service to patients who need it. Would MHCC be inviting applications for new programs even though there is no ability to supply that service? Ms. Sullivan added that having the need calculation show a potential need does not necessarily guarantee the approval of a CON. Ms. Goldman agreed. Ms. Fleck suggested that, if the SHP chapter follows that approach, is it important to determine policies regarding the right capacity for an organ transplantation program and the volumes that a new program should be able to achieve.

Dr. Klassen asked for clarification on the need methodology. Ms. Fleck responded that Staff calculates the historical change in the utilization rate for the population over a previous three year period, and assumes the same trend will carry forward in the next three years. It is fairly simple. Ms. Weiland wanted to make sure she understood that the methodology looked at the demand side for a procedure without taking into account the organ availability and capacity of different programs. Ms. Goldman thought it might be more accurate to say the methodology reflects program capacity and supply, rather than the volume of patients who need an organ transplant. Ms. Fleck agreed. Ms. Weiland added that it was important to understand that it does not reflect what the transplant centers could do; the existing transplant centers could perform more transplants if they had more organs. Ms. Goldman agreed that it does not take into account that existing centers could have the capacity to absorb net need. The current need methodology also uses only two year-to-year rate changes to calculate a future rate change forward. If there is one year of significant change in the volume, then it will affect the trend that the current methodology assumes. Ms. Fleck explained that there has to be a sharp increase in order to project sharp growth in the demand for transplants, and if there is going to be sharp growth, then maybe you need a new program.

Ms. Weiland commented that the allocation policies, in liver specifically, have allowed both Maryland programs to transplant more Maryland recipients because the transplant programs are now able to import more organs from outside of the area. These policies provided more access to Maryland residents in the last two years, which are not reflected in the most recent need projection, which only includes 2012 data. She believes the projection should be updated in order to see this latest trend and have this discussion. Ms. Fleck responded that MHCC tries to keep the projections updated and she knows that the 2013 data is available and the 2014 data would be available in March from UNOS.

Dr. Klassen believes it might be best to consider the need projection, despite its imperfections, as just a set point to determine when a CON application could be considered. Ms. Goldman asked if there was any more feedback on the need methodology from the members at this point. Ms. Weiland said that she could understand how looking at historical data makes sense for some services, like cardiac surgery, but she is not sure it makes sense for organ transplantation because of the fixed pool of organs.

Ms. Sullivan added that she thought they were missing a discussion about the potential for living donations. She pointed to the data presented that indicate Maryland centers are doing a significant number of living donation transplants. The current need calculations are using historical volumes to project the future, without challenging each of the areas to do more than they have done in the past. If a population is underserved, the need calculation projects that this trend will continue, and the population will always be underserved. She does know the formula and has replicated the methodology herself. She thinks it misses an opportunity to address populations that have been historically underserved and could be better served with more living donation and with more disease prevention.

Ms. Weiland commented that she believes the numbers for donations have been relatively flat across the country and wondered whether Maryland was ahead of this trend. She also added

that a difference in rates of living donation from region to region does not mean that the centers are not doing everything they can to promote these donations. Ms. Sullivan believes the current methodology and SHP chapter standards prevent the ability to really ask that question because there is no opportunity for a new program to apply for a CON if the net need is not demonstrated, even though the area may be underserved. Ms. Weiland suggested that was a policy issue with the SHP chapter, and there may be potential to improve policies.

Ms. Fleck explained that she is interested in creating a policy that is in the best interest of Marylanders, so she wants to find out if work group members believe there should be more emphasis on living donors when MHCC projects the need for kidney transplantation. She encouraged the group to discuss changes to the need methodology, standards, and policies. Ms. Goldman added, for example, that if need projections are based on the number of patients with end stage organ failure, then MHCC would need additional standards to help guide them in determining at what point a new programs may be needed.

Dr. Donovan said that was a hard question to answer because a determining factor is that there are not enough organs to give to the people who are on the list. Ms. Weiland added that the dilemma is that there is a fixed pool of deceased donors, and there are options for living organs, but adding another center does not give more patients access. Ms. Sullivan reported that she has research that shows that when there are multiple transplant centers in a given OPO, the total number of donors and organs increases. She thinks that describing the donor pool as fixed is an easy way out. There may be more creative ways to tap into donor pools and increased institutional commitment levels. Ms. Weiland asked Ms. Sullivan to share the data to which she was referring, and she agreed to share it. Dr. Klassen added that regardless of whether the pool was considered fixed or not, it still has not changed over the years. If the volume increased in Baltimore, it went down somewhere else.

Ms. Ostovitz expressed that she is hopeful that the new UNOS policies will allow organs to be transplanted faster to sicker patients, not just redistributed. She is interested in better utilizing the finite resources without having to build another center or program. Her program spent thousands and thousands of dollars in the past year to change their wait list process and provide UNOS with the required data, so she hopes the changes will work. Dr. Klassen reported that the changes have been in effect for one month and two days, so they will see if those policy changes worked over the next 10 years.

Ms. Sullivan reiterated that she would like to see a SHP that allows a program to propose and demonstrate how it will impact and improve organ transplantation, as is done in some other states. Ms. Fleck asked if there was anything that Staff could do or look into further to help facilitate more discussion on this issue. Ms. Ostovitz asked to better understand why some other states chose to limit the number of organ transplant programs per planning region. Ms. Goldman responded that by limiting the number of transplant programs per region, the state is assuming that the existing center can absorb new need or demand. Ms. Fleck commented that such an approach would simplify the discussion about whether a new program was needed.

Mr. Parker added that Virginia has five large regions, including two regions with two million people. The standards in Virginia's plan may be more of an historical, political artifact. When Virginia began regulating organ transplantation through CON, there were two academic medical centers that had established programs. Planners may have wanted to create a standard that supported keeping those centers. Dr. Donovan confirmed that this type of planning is done based on geography in Virginia. Likewise, in Maryland, no one is proposing that if you have an area that is more than two hours away from a center and you have more need in that area, that increases the ability to establish a program there, as opposed to establishing a program in the middle of an area that has a lot of organ transplant opportunities within that two hour window. Mr. Parker does not believe the health care infrastructure in Maryland lends itself to that sort of geographical and population-based regionalism. Maryland has the I-95 corridor creating north-south access for the surrounding population. The population density drops so quickly beyond that corridor, it is hard to see the argument for building an organ transplantation center in Western Maryland or the Eastern Shore.

Mr. Parker thought staff could run some scenarios looking at alternative approaches. He considers what MHCC does now as a fairly simple study of case volume and how it is trending. If it's trending down, there is no need for additional programs. If it is trending up enough, that is the first step in opening up the consideration to establish new programs. The net need also has to exceed the minimum volume requirement. He commented that he sees a conflict in the current SHP chapter with a need methodology that seems to invite an application, while there is a policy statement that implies MHCC should not consider new programs because established programs should be able to absorb new demand. It gives preference to larger and established programs, even though established programs do not need regulatory approval to expand.

Mr. Parker proposed that an alternative is to continue to look at how case volumes are trending, but in a more sophisticated way. For example, if deceased donor organs are flat, but living donor organs are increasing over time, Staff could calculate separate use rates and trends to come up with an aggregate number. Volume could be one criterion, but there could also be an opportunity to accept applications based on quality issues at an existing program. He noted that the work group would have to define the critical quality issues for this approach.

Ms. Ostovitz responded that the transplant programs are already so heavily regulated by CMS, UNOS, and the Joint Commission that her program has had to hire additional staff to monitor and audit quality reporting. She suggested that a review of the Medicare and UNOS quality requirements might be used, without additional requirements. Both Mr. Parker and Ms. Fleck agreed that MHCC does not want to institute a new data collection, reporting, or monitoring process. Mr. Parker explained that he only wanted to point out that the current SHP chapter strongly relates quality with volume. Based on what Dr. Klassen said, Mr. Parker thinks that might have changed. Ms. Ostovitz responded that quality has been a recent focus of the new reporting requirements. Mr. Parker responded that it may not make sense to include a quality check because all programs are high quality, but he would like to find a meaningful way to address the issue. He added that, as the work group talks about revising the need projection, members could consider these things because MHCC is seeking ideas to incorporate into a

revised methodology. Ms. Fleck suggested that Staff respond with a few scenarios regarding these issues.

10.24.15 Policies regarding Patient Education and Advocacy for Increased Donations

Ms. Goldman suggested going over the last agenda item quickly. The workgroup members agreed. Dr. Callender expressed his desire to talk more about the SHP chapter policies that focus on quality. Policy 3 in the SHP chapter for organ transplants advocates for increased prevention and early detection of factors leading to end stage organ failure. Dr. Callender agreed that was important, but he would like to see it go farther. Ms. Goldman asked how, specifically, workgroup members felt that the SHP chapter could accomplish the goals described in Policy 3. Dr. Callender commented that he would like to see a reference to the promotion of increased organ donation. Ms. Goldman agreed it was good idea and noted that Policy 13 expresses support for the Maryland Organ and Tissue Donation Fund. Dr. Callender asked where money from that fund is spent. Ms. Goldman responded that she would follow up on that and asked if there were other funds or campaigns that workgroup members would advise should be included in an updated policy. Dr. Klassen asked if they needed to be based in Maryland. Ms. Goldman and Ms. Fleck responded that it is not necessary, and that Staff would be interested in hearing suggestions. Ms. Goldman asked workgroup members to send or give her suggestions after the meeting, since it was already past the scheduled end time for the meeting.

Next Meeting

Ms. Fleck suggested that the group revisit the need methodology at the next meeting, which will likely be in April. She added that Staff will work on an updated need projection and more specific scenarios that could be discussed. Ms. Weiland asked Ms. Fleck if she had an idea of how many meetings will be held. Ms. Fleck responded that three or possibly four meetings would be held, but she did not see the need for this work group to go beyond that point. She noted that some information can also be distributed via email, and MHCC may give the workgroup a draft of the updated chapter for feedback before it is released for public comment. Ms. Fleck thanked everyone for their participation and concluded the meeting shortly after 3 pm.